Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

The effect of propranolol on post-traumatic stress and clinical outcomes in burn patients

Protocol summary

Study aim
The effects of propranolol on clinical outcomes in patients with post-traumatic stress and burns

Design
Clinical trial with control and intervention group, specific randomized, phase 3 on 52 patients. Blocking was used for randomization

Settings and conduct
After receiving an official letter from the University of Medical Sciences and Informed consent in writing of each patient sample available in 24 hours by a doctor burn experienced penetrated check routine based on the inclusion criteria for the study are .During 48 hours of hospitalization, after stabilizing the hemodynamic status and fluid therapy, they are treated in the intervention group and the control group by randomly assigned random sampling using block blocking.

Participants/Inclusion and exclusion criteria
Inclusion criteria have wounds that 20 to 50% of the total body surface area TBSA and second and third degree , need treatment with at least one skin graft surgery, 48 hours after hospitalization in the intervention group to receive propranolol for at least 4 consecutive days, satisfaction with participating in data collection

Intervention groups
In the control group, patients are treated with standard burn care. Propranolol administration by specialist burns unit and after consultation with the doctor's advice heart for oral or nasal cannula with the same dose of 10 mg twice daily at 6 am and evening with monitoring vital signs routinely match. Daily monitoring of hemodynamic status (heart rate and blood pressure of the left hand using non-invasive cuff measurement) is performed before drug administration in the intervention group and after drug administration routinely in both groups in the wards.

Main outcome variables
Post-traumatic stress, Hemoglobin and hematocrit, Successful skin grafting, Average length of hospital stay

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190919044819N2**
Registration date: **2020-09-13, 1399/06/23**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-13, 1399/06/23**
Update count: **0**

Registration date
2020-09-13, 1399/06/23

Registrant information

Name
narges hosseini

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7768 4704

Email address
nargeshossini123@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-15, 1399/05/25

Expected recruitment end date
2021-04-15, 1400/01/26

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effect of propranolol on post-traumatic stress and clinical outcomes in burn patients

Public title

The effect of propranolol on post-traumatic stress and clinical outcomes in burn patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Able to talking Wounds that are 20 to 50 percent of the total body surface area of TBSA And have wounds that are second and third degree Requires treatment with at least one skin graft surgery Receive propranolol for at least 4 consecutive days 48 hours after hospitalization in the intervention group Satisfaction with participating in data collection

Exclusion criteria:

Medical conditions Contraindications to propranolol (beta-blocker contraindication) pregnancy bipolar disorder, head injury cardiopulmonary disease, endocrine and peripheral, asthma, systolic blood pressure less than 90, heart rate 60, inhalation damage 5 years of malignancy, history of AIDS, diabetes

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

patients are treated with standard burn care.Allocated random sampling using block classification in two groups of 52 blocks including 26 participants in the intervention group and 26 participants in the group will be witnessed. In the intervention group treated with propranolol to patients treated with standard of care of the burn begins. In the control group, patients are treated with standard burn care.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical Sciences

Street address

Shahid Bahonar Boulevard, Qazvin University of Medical Sciences

City

gazvin

Province

Qazvin

Postal code

34417431874

Approval date

2020-07-26, 1399/05/05

Ethics committee reference number

IR.QUMS.REC.1399.195

Health conditions studied

1

Description of health condition studied

burn

ICD-10 code

T21.21XD

ICD-10 code description

Burn of second degree of chest wall, subsequent encounter

Primary outcomes

1

Description

post-traumatic stress

Timepoint

At the beginning of the study (before the intervention) and And one month after the intervention

Method of measurement

Impact of Event Scale-Revised

Secondary outcomes

1

Description

Successful skin grafting

Timepoint

Both groups will be evaluated within two weeks and four weeks after discharge

Method of measurement

Clinical examination in which the evaluation of the success of the transplant means a transplant that is pink in color and firmly attached to the base of the transplant area.

2

Description

Duration of hospitalization

Timepoint

The first and last day of hospitalization in the ward

Method of measurement

Counting by number of days

Intervention groups

1

Description

Intervention group: The intervention in this study includes the administration of propranolol by a physician specializing in burns and after consultation with the advice of a cardiologist orally or through the nasal tube with the same dose of 10 mg twice a day at 6 am and evening. Vital symptom control is routinely adjusted, and daily monitoring of hemodynamic status (heart rate and left hand blood pressure using non-invasive cuff measurements) is administered before drug administration in the intervention group and after drug administration routinely in both. The group is done in sections.

Category

Treatment - Drugs

2

Description

Control group: Burn patients are treated with standard burn care

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Hospital

Full name of responsible person

Leili Yekefallah

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Qazvin University of Medical Sciences, Bahonar,Qazvin,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Leili Yekefallah

Position

Assistant Professor of Qazvin Nursing School

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
The effect of propranolol on post-traumatic stress and clinical outcomes in burn patients
When the data will become available and for how long
6 months after printing the results
To whom data/document is available
Qazvin University of Medical Sciences Pregnancy Burn treatment centers
Under which criteria data/document could be used
Through a valid university site
From where data/document is obtainable
Qazvin- Qazvin University of Medical Sciences- School of Nursing and Midwifery
What processes are involved for a request to access data/document
Send authors email
Comments